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IP

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR		ATTORNEY DOCKET NO.
09/262,506	03/02/99	PERLIN	M	PERLIN-3CONT

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EXAMINER	
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ART UNIT	**PAPER NUMBER**
1631	7

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/262,506	Applicant(s) PERLIN, MARK W.	
	Examiner Mary K Zeman	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

1)☒ Responsive to communication(s) filed on *28 July 2000* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16-33* is/are pending in the application.

4a) Of the above claim(s) *32 and 33* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims *16-33* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☐ All b)☐ Some * c)☐ None of the CERTIFIED copies of the priority documents have been:

1.☐ received.

2.☐ received in Application No. (Series Code / Serial Number) _____ .

3.☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

15)☒ Notice of References Cited (PTO-892)
16)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18)☐ Interview Summary (PTO-413) Paper No(s). _____ .
19)☐ Notice of Informal Patent Application (PTO-152)
20)☐ Other: .

DETAILED ACTION

Applicant's election with traverse of Group I, claims 16-31 in Paper No. 6 is acknowledged. The traversal is on the ground(s) that the same patentable feature is found in both groups, and that a search of both Inventions would not pose an undue burden upon the examiner. This is not found persuasive because each method has differing steps and differing ultimate goals such that further searching would be required for the second Invention that is not necessarily required for the first invention.

The requirement is still deemed proper and is therefore made FINAL.

Claims 32 and 33 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 6.

Priority

Acknowledgment is made of applicant's claim for priority under 35 U.S.C. 120 to prior applications filed in the U.S.

Drawings

This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

Specification

The abstract of the disclosure is objected to because it is more than one page in length. The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 250 words. It is important that the abstract not exceed 250 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The metes and bounds of the phrase "performing an operation on a nucleic acid molecule" in claim 16 are unclear. The term "operation" can have a variety of definitions ranging from surgery to a mathematical function, each of which cannot be performed on a nucleic acid. These are reasonable interpretations of the term "operation" in view of the use of the term "operating" in step (d) to indicate a computer based mathematical function, and not a scientific assay or experiment on a polynucleotide. Further, operations like PCR or hybridization cannot work with a *single nucleic acid* as claimed (e.g. A, T, C or G)- a polynucleotide or polynucleic acid are required.

Claim 16 (e) recites the limitation "a nucleic acid component of the experiment" in reference to step (a). There is insufficient antecedent basis for this limitation in the claim. Claim 16 does not set forth "an experiment" or a sample that may comprise "a nucleic acid component."

The metes and bounds of claim 18 are unclear. Are the PCR primers the nucleic acid molecules being operated upon in step (a), or are the primers used to act upon a polynucleotide present in a sample?

Claim 19 does not appear to further limit the claim from which it depends- it would appear that a genetic marker, by its very nature, is polymorphic (different in sequence for

different individuals of a population). Therefore, a claim stating that fact merely recites a property already claimed in the previous claim.

Claim 20 recites the limitation "the nucleic acid component" in reference to claim 16. As set forth above, there is insufficient antecedent basis for this limitation in the claim.

Claim 22 recites the limitation "the PCR products are labeled" in reference to claim 17. There is insufficient antecedent basis for this limitation in the claim. There is no recitation of any products of any PCR reaction in claim 17 or 16 from which claim 22 ultimately depends. Further it is unclear whether it is the primers that are labeled, or the polynucleotides that result from a PCR reaction in a sample that are labeled.

Claim 24 places the further method step in the wrong place in the method of claim 16. The data generated in step (b) must be represented as a signal before it can be stored in the memory of a computer, as computer memory is made up of electrical signals, and not analog data.

Claim 28 is vague and indefinite in its entirety. The automatic analysis of claim 16 does not provide a "positionally cloned gene" in any manner. The data generated after the final analysis may provide information used to locate the position of a genetic marker on a chromosome, however, no cloning steps take place. "Cloning a gene" requires generating a cDNA library which comprises the gene of interest, and screening the library for a positive clone, then isolating the specific cDNA encoding the gene, then going back to determine the location of the gene in the genome of the organism. None of these steps are present or disclosed in the specification. Applicant's intent with this claim is completely unclear.

In claim 29, is the individual who is fingerprinted the same individual who provided the nucleic acid in claim 16? No such individual or source of a sample is set forth in claim 16 such that the data generated would have any relevance to any given individual.

The metes and bounds of the phrase "means for performing an operation on a nucleic acid molecule" in claim 30 are unclear. The term "operation" can have a variety of definitions ranging from surgery to a mathematical function, each of which requires differing and potentially mutually exclusive means for performing it, and which further cannot be performed on a nucleic acid. These are reasonable interpretations of the term "operation" in view of the use of the term "operating" in step (d) to indicate a computer based mathematical function, and not a scientific

assay or experiment on a polynucleotide. Further, operations like PCR or hybridization cannot work with a *single nucleic acid* as claimed (e.g. A, T, C or G)- a polynucleotide or polynucleic acid are required.

Claim 30 (e) recites the limitation "a nucleic acid component of the experiment" in reference to step (a). There is insufficient antecedent basis for this limitation in the claim. Claim 30 does not set forth "an experiment" or a sample that may comprise "a nucleic acid component."

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 16-31 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 5,541,067. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method steps of the '067 patent meet the limitations of the pending claims in the present application. Step (a) of claim 16 of the instant invention, "performing an operation on a nucleic acid molecule" is met by step (b) of claim 1 of the patent. Step (b) "generating data" of the instant invention is met by step (d) of claim 1 of the patent. Step (c) "representing the data as an electrical signal" of the instant invention is met by step (d) of claim 1 of the patent. Step (d) of the instant invention "operating on the electrical signal to identify a subsignal" in the instant application is met by step (e) of claim 1 of the patent, and finally, Step (e) of the instant

invention "analyzing a physical property of the nucleic acid" is met by step (f) of claim 1 of the patent.

Claims 16-31 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22 of U.S. Patent No. 5,580,728. Although the conflicting claims are not identical, they are not patentably distinct from each other because the methods of the patent fall within the scope of the instant invention. Step (a) of claim 16 of the instant invention, "performing an operation on a nucleic acid molecule" is met by step (b) of claim 1 of the patent. Step (b) "generating data" of the instant invention is met by step (d) of claim 1 of the patent. Step (c) "representing the data as an electrical signal" of the instant invention is met by step (d) of claim 1 of the patent. Step (d) of the instant invention "operating on the electrical signal to identify a subsignal" in the instant application is met by step (e) of claim 1 of the patent, and finally, Step (e) of the instant invention "analyzing a physical property of the nucleic acid" is met by step (f) of claim 1 of the patent.

Claims 16-31 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-30 of U.S. Patent No. 5,876,933. Although the conflicting claims are not identical, they are not patentably distinct from each other because the methods of the patent fall within the scope of the instant invention. Step (a) of claim 16 of the instant invention, "performing an operation on a nucleic acid molecule" is met by step (b) of claim 1 of the patent. Step (b) "generating data" of the instant invention is met by step (d) of claim 1 of the patent. Step (c) "representing the data as an electrical signal" of the instant invention is met by step (d) of claim 1 of the patent. Step (d) of the instant invention "operating on the electrical signal to identify a subsignal" in the instant application is met by step (e) of claim 1 of the patent, and finally, Step (e) of the instant invention "analyzing a physical property of the nucleic acid" is met by step (f) of claim 1 of the patent. Further, claims 3-6 of the patent specifically claim deconvoluting steps for analysis of the data generated, the operations performed in the patent are PCR, the products can be labeled with a detectable label, and physical properties of the nucleic acid in the sample are determined.

Claims 16-31 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6,054,268. Although the conflicting claims are not identical, they are not patentably distinct from each other because the methods of the patent fall within the scope of the instant invention. Step (a) of claim 16 of the instant invention, "performing an operation on a nucleic acid molecule" is met by step (b) of claim 1 of the patent (separating the DNA fragments by size). Step (b) "generating data" of the instant invention is met by step (c) of claim 1 of the patent (detecting the labeled DNA). Step (c) "representing the data as an electrical signal" of the instant invention is met by step (d) of claim 1 of the patent (obtaining information from the size separation). Step (d) of the instant invention "operating on the electrical signal to identify a subsignal" in the instant application is met by step (e) of claim 1 of the patent (operating on the data collected), and finally, Step (e) of the instant invention "analyzing a physical property of the nucleic acid" is met by step (f) of claim 1 of the patent (determining the size of the DNA fragment).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 16, 24, 27, 30 and 31 are rejected under 35 U.S.C. 102(e) as being anticipated by Weiss et al. (USP 5,470,710).

Claim 16 sets forth a method for analyzing data which comprises (a) performing an operation on a nucleic acid; (b) generating data from the operation; (c) representing the data as an electrical signal; (d-e) using a computing device to analyze the electrical signals. The generating step records the information into a computer, and the analyzing step characterizes a

physical property of the nucleic acid. Claims 30 and 31 are drawn to a system for performing the method of claim 16.

Weiss et al. (USP 5,470,710, filed 10/22/93) discloses a method for automatically analyzing data from a sequencing reaction. The methods of Weiss include: (a) performing a sequencing reaction on a nucleic acid sample; (b) generating data from a gel electrophoresis (for size) of the labeled sequencing reaction; (c) the data is represented as an electrical signal in a computing device, and then (d-e) the electrical signal is converted to a linear string of nucleotides representing the physical sequence of nucleotides in that sample. This is outlined in column 4 of Weiss et al., and the system designed to carry out this method is outlined at columns 5-6 of Weiss et al. The specifics of the data analysis of Weiss et al. are set forth in Example 3, at columns 9-10.

Claims 16-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Schwatrz et al. (Schwartz et al. 1992 Am. J. Hum. Genet. 51: 721-729, 1992).

The claims are drawn to methods of genotyping a nucleic acid sample, using PCR to generate labeled reaction products which are analyzed, and the data from the analysis is operated upon to obtain information about a physical property of that nucleic acid sample, and thus produce a genotype. The steps are as set forth above.

Schwartz et al. (Schwartz et al. Am. J. Hum. Genet. 51: 721-729, 1992) discloses methods of performing linkage analysis for a genetic STR marker for Duchenne's Muscular Dystrophy. A nucleic acid sample from an individual is subjected to PCR with labeled primers, resulting in labeled PCR products. The labels from the PCR products were recorded as an electrical signal (computerized traces of voltage readings, p 724). Then, a computing device performed a deconvoluting operation on the data: PCR-based linkage analysis. They physical property analyzed is the physical size of a particular CA repeat, and a particular pattern of CA repeat size can fingerprint an individual at that locus. Schwartz et al. also disclose a system for performing these methods at page 726, in the Discussion section.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary K Zeman whose telephone number is (703) 305-7133. The examiner can be reached between the hours of 7:30 am and 5:00 pm Monday through Thursday, and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at (703) 308 4028.

The fax number for this Art Unit is (703) 305-7401.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Tech Center receptionist whose telephone number is (703) 308-0196.

Mary Zeman
Examiner, 1631

mkz
October 12, 2000